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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,014	10/21/2003	Scott E. Boatman	8627-325	9347

7590 09/02/2005

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EXAMINER

GHERBI, SUZETTE JAIME J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 09/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/691,014

Applicant(s)

BOATMAN, SCOTT E.

Examiner

Suzette J. Gherbi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2005 and 20 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 12, 14, 16, 18, 19, 27, 29-31 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 12, 14, 16, 18, 19, 27, 29-31 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/20/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's response and amendments dated 2/11/05 and 6/20/05 have been received in application serial number 10/691,014. Claims 2-11, 13, 15, 17, 20-26, 28, 32-38 and 40 have been canceled.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 18 recites the limitation "said plurality of openings". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 12, 19, 27, 31 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abraham et al. 2003/0171824 in view of Schaldach et al.

2002/0123793. Abraham et al. discloses the invention as claimed comprising: A cannula [0017] formed from at least a first layer and a second layer [0018... *two or more layers...*], wherein the first layer and second layer each are made of different non-synthetic [0011... *or from different collagen materials...*], natural tissue without the presence of a synthetic support structure; wherein the cannula comprises an opening extending through a wall defined by the first layer and second layer; made of small intestine submucosa [0014-0016]; including growth factors [0018 pg. 3 growth factors]. However Abraham et al. does not specify that the second layer is cartilage. Schaldach et al. teaches a tubular conduit for vascular use manufactured from cartilage (see [0012; 0018; 0021; 0042; 0053; 0060; 0068]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the inventions of Abraham et al. and incorporate a layer of cartilage (by any alternating layer design) because Abraham discloses in section [0011] that two or more different types of material having collagen may be utilized for the layers and that they may be bonded together and Abraham also discloses that the material may be layered with other materials to form as stent [0019].

7. Claims 14, 16, 29 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abraham et al. in view of Yang 6,613,082. Abraham et al. have been disclosed above however they do not specify the use of Paclitaxel. Yang teaches a stent graft with a protein matrix that utilizes Paclitaxel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a drug and specifically Paclitaxel in the invention of Abraham et al. mentions in section that [0036] that drug delivery graft are contemplated and because it is well known that Paclitaxel is used to treat restinosis on stents implanted into blood vessels.

8. Claims 18, 30 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abraham et al. in view of Sabolinski 2004/0002772. Abraham et al. structure has been disclosed above including the inclusion of perforations/openings. Sabolinski teaches a tubular bi or tri-layered implant made from small intestine material [0011] that also has perforations formed by utilizing a laser [0024] The claimed phrase "formed by cutting through the wall with a laser" is being treated as a product by process limitation; that is that the openings of Abraham et al. can be made by laser cutting. As set forth in MPEP 2113 product by process claims are not limited to the manipulation of the recited steps, only to the structure implied by the steps..

Response to Arguments

9. Applicant's arguments filed 2/11/05 have been fully considered but they are not persuasive. Applicant has canceled multiple dependent claims and has incorporated the previously rejected claim limitations into some of the dependent claims. Applicant has then repeated each new independent claim and sums up the response by saying that the prior art disclose the specific structures. The examiners opinion with regards to the claims has been stated above. Abrahams discloses a natural tissue tubular device that can be implanted into the vasculature and can have two or more layers. This meets the limitations of a first, second and third layer. In response to applicant's argument that there is no suggestion to combine the references (because it would be hindsight), the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the modification is utilizing cartilage as taught by Schaldach et al. for the second layer between the submucosa layers because Abrahams states in section [0011] that collagen materials may be utilized as one of the layers (collagen comes from cartilage) and in section [0034] it states that cells may be populated into the structure such as cartilage therefore it is no beyond reason to combine ILC of Abrahams with a cartilage middle section.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


11. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.

13. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

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14. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


Suzette J-J Gherbi
29 August 2005